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## NOTICE OF ALLOWANCE AND FEE(S) DUE

27387

7590

08/25/2010

LONDA, BRUCE S. NORRIS MCLAUGHLIN & MARCUS, PA 875 THIRD AVE, 8TH FLOOR NEW YORK, NY 10022

EXAMINER				
STAPLES, MARK				
ART UNIT	PAPER NUMBER			

1637

DATE MAILED: 08/25/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.

10/573,134 12/18/2006 Pablo Steinberg 101215-219 4520

TITLE OF INVENTION: METHOD FOR CONDUCTING NON-INVASIVE EARLY DETECTION OF COLON CANCER AND/OR OF COLON CANCER PRECURSOR CELLS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	11/26/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

### Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450 (571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 27387 7590 08/25/2010 Certificate of Mailing or Transmission LONDA, BRUCE S. I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. NORRIS MCLAUGHLIN & MARCUS, PA 875 THIRD AVE, 8TH FLOOR NEW YORK, NY 10022 (Depositor's name (Signature (Date APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/573,134 12/18/2006 Pablo Steinberg 101215-219 4520 TITLE OF INVENTION: METHOD FOR CONDUCTING NON-INVASIVE EARLY DETECTION OF COLON CANCER AND/OR OF COLON CANCER PRECURSOR CELLS APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional YES \$755 \$300 \$0 \$1055 11/26/2010 **EXAMINER** ART UNIT CLASS-SUBCLASS STAPLES, MARK 1637 435-091200 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_\_ (enclose an extra copy of this fo Advance Order - # of Copies \_ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/573,134	12/18/2006	Pablo Steinberg	101215-219	4520	
27387 75	27387 7590 08/25/2010		EXAMINER		
LONDA, BRUCE S.			STAPLES, MARK		
NORRIS MCLAUGHLIN & MARCUS, PA 875 THIRD AVE, 8TH FLOOR NEW YORK, NY 10022		ART UNIT	PAPER NUMBER		
		1637 DATE MAILED: 08/25/201	0		

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 288 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 288 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
	10/572 124	STEINIBERG ET AL	
Notice of Allowability	10/573,134 <b>Examiner</b>	STEINBERG ET AL. Art Unit	
	MARK OTARIES	1007	
	MARK STAPLES	1637	
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIOF of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in or other appropriate commitments. This application is	n this application. If not included unication will be mailed in due course. <b>THIS</b>	⁄e
1. This communication is responsive to <u>06/23/2010</u> .			
2. The allowed claim(s) is/are <u>1-6,9 and 11-14</u> .			
<ul> <li>3. Acknowledgment is made of a claim for foreign priority ureal.</li> <li>a) All b) Some* c) None of the:</li> <li>1. Certified copies of the priority documents have</li> <li>2. Certified copies of the priority documents have</li> <li>3. Copies of the certified copies of the priority documents</li> </ul>	been received. been received in Applicati	on No	
International Bureau (PCT Rule 17.2(a)).			
* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		e a reply complying with the requirements	
4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give			
5. CORRECTED DRAWINGS ( as "replacement sheets") mus	st be submitted.		
(a) $\square$ including changes required by the Notice of Draftspers	on's Patent Drawing Revie	w ( PTO-948) attached	
1) 🔲 hereto or 2) 🔲 to Paper No./Mail Date	•		
(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date	s Amendment / Comment o	r in the Office action of	
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t			
6. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT			
Attachment(s) 1. ☑ Notice of References Cited (PTO-892)	5. ☐ Notice of I	nformal Patent Application	
2. Notice of Draftperson's Patent Drawing Review (PTO-948)	6. ☐ Interview S	Summary (PTO-413),	
3. ☐ Information Disclosure Statements (PTO/SB/08),	Paper No 7.	/Mail Date Amendment/Comment	
Paper No./Mail Date4.	8. 🛛 Examiner's	Statement of Reasons for Allowance	
of Biological Material	9.	<b>→</b>	
/Mark Staples/			_
Primary Examiner, Art Unit 1637 08/11/2010			

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## **DETAILED ACTION**

1. Claims 1-6, 9, and 11-14 are pending and at issue.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

## **Declaration Effective**

- The declaration under 37 CFR 1.132 filed 06/23/2010 is sufficient to overcome the rejection of claims 1-6, 9, and 11-14 based upon Salahshor et al. (1999), Davies et al. (June 2002), Kmiec et al. (WO200173002 published 2001), Shuber et al. (WO200118252 published 2001), Ferrie et al. (GB2327497 published 1999), Coste et al. (1998), Nollet et al. (1996), Albertsen et al. (United States Patent 6,114,124 issued 2000), Ikawa et al. (1988), McCormick (1999), Buck et al. (1999), and Stratagene (1988).
- 3. The article from the journal Cancer Epidemiology referenced in the declaration as an enclosure was not found in the record and is provided along with the attached PTO-892 form, for entry into the record.

# Objections and Rejections that are Withdrawn

4. Objections and rejections not reiterated herein are hereby withdrawn. Applicant's declaration has overcome the rejections under 35 U.S.C. 103.

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## **Claims Allowed**

5. Claims 1-6, 9, and 11-14 are allowed.

6. The following is an examiner's statement of reasons for allowance: no prior art was found which teaches or fairly suggests the improved methods and kit for early detection of colon cancer using the panel of primers as claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## **Close**

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Staples/ Primary Examiner, Art Unit 1637 08/11/2010